

K073349

510(k) Summary

Bret M. Berry
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FEB 13 2006

Contact: Bret M. Berry
Member-Manager

Common or Usual Name:	Anterior Lumbar Buttress System
Proposed Proprietary or Trade Name:	Reliance Buttress Washer System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR 888.3060
Product Code:	KWQ

Substantial Equivalence

The Reliance Buttress Washer is substantially equivalent to the legally marketed Synthes Titanium Locking Plate System (K970048), the Medtronic Sofamor Danek Bone Graft Washer (K994122, K041217), the DePuy BowTi Anterior Buttress Staple System (K021039), the SeaSpine Anterior Lumbar Buttress System (K040130), and the Altiva ALTEST™Anterior Buttress Plating System (K061482). The Reliance Buttress Washer is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and use with supplemental fixation.

Device Description

The Reliance Buttress Washer System is a temporary implant used to prevent bone graft extrusion. The Reliance Buttress Washer Systems consists of washers and bone screws. The Buttress Washer is also intended to provide stabilization and augment development of a solid spinal fusion. The Buttress Washer fixates to the anterior portion of the thoracolumbar vertebral body. The construct may be employed alone device or with other anterior, anterolateral, or posterior spinal systems made of compatible materials.

Intended Use/Indications for Use

The Reliance Buttress Washer System is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

Reliance Medical Systems, LLC
% Mr. Bret M. Berry
Member-Manager
2647 Cassowary Circle
Sandy, UT 84092-7116

Re: K073349

Trade/Device Name: Reliance Buttress Washer System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: Nov 21, 2007
Received: Dec 31, 2007

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Reliance Buttress Washer System _____

Indications for Use:

The Reliance Buttress Washer System is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

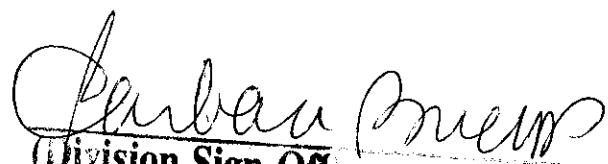
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off
**Division of General, Restorative,
and Neurological Devices**

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